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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/770,117 | 02/02/2004 | Jay A. Berzofsky | 14014.0347U3 | 9347 |

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NATIONAL INSTITUTE OF HEALTH
C/O NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30303

| EXAMINER | |
|---|---|
| LUCAS, ZACHARIAH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/770,117 | BERZOFSKY ET AL. | |
| | Examiner | Art Unit | |
| | Zachariah Lucas | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 02 February 2004.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 21-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 21-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5-17-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Currently, claims 21-30 are pending and under consideration.

### *Inventorship*

2. In view of the papers filed March 4, 2005, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the deletion of Charles D. Pendleton.

It is noted that the Applicant has also requested the deletion of Tatsumi Arichi as co-inventor. However, Dr. Arichi was not identified as an inventor in the original Oath/Declaration filed in this application on February 2, 2004, and was therefore never a co-inventor in this application. As Dr. Arichi was never a named inventor in the present application, he cannot be removed as such.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### *Priority*

3. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed as PCT/US99/18674 on August 17, 1999. A claim for priority

under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

It is further noted that the application does not meet the conditions for claiming priority to this application under 35 U.S.C. 120, as neither the specification nor an Application Data Sheet provide the required reference to this earlier application.

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

This application is claiming the benefit of a prior filed provisional application under 35 U.S.C. 119(e). In order to claim benefit to such an provisional application, the non-provisional application must be filed within 12 months of the filing date of the provisional application (or claim priority to an application filed within this time period and claiming priority to the provisional application). In the present case, as the Applicant has not properly claimed priority of the filing date of PCT/US99/18674 under 35 U.S.C. 120, but has claimed priority to this PCT under 35 U.S.C. 119 (a), the applicant has not met the requirements for claiming priority to the provisional application. The Applicant is therefore not awarded priority to this earlier application.

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as described above. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and

(a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371 (b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application.

A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional.

### *Claim Rejections - 35 USC § 101*

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 22-24, and 29-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims read on any compositions comprising the indicated proteins or polypeptides and a carrier, or on compositions comprising vectors encoding such polypeptides. The claims do not require that the peptides, proteins, or vectors are isolated, and therefore read on human beings comprising such proteins or polypeptides. The claims therefore read on non-statutory subject matter.

It is suggested that the claims be amended to read on compositions comprising isolated hepatitis C core polypeptides or an isolated vectors.

### *Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 21, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarobe et al. (J Clin Invest 102: 1239-48- of record in the IDS of May 2004). These claims read on compositions comprising an isolated peptide of SEQ ID NO: 1. Such peptides, and compositions

comprising them are disclosed in the Sarobe reference as the 8A variant peptide. See e.g., abstract, and page 1243 (teachings immunization with compositions comprising the peptides). The reference therefore anticipates the indicated claims.

This rejection is made because the present application has not correctly claimed priority to the earlier filed PCT application PCT/US99/18674, and therefore has also not met the requirements for claiming priority to earlier U.S. provisional application 60/097446.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 25, 26, 28-30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarobe as applied to claims 21-24 above, and further in view of Chisari et al., (U.S. 5,709,995- of record in the May 2004 IDS). These claims are drawn to isolated polynucleotides, and vectors comprising such, that encode the peptide of SEQ ID NO: 1. The teachings of Sarobe have been described above. While this reference teaches the peptide of SEQ ID NO: 1, the reference teaches the synthesis of these peptide rather than recombinant production of the peptides using polynucleotides encoding them.

However, Chisari teaches the production of a similar peptide to SEQ ID NO: 1 through recombinant means. See, columns 5-6 (disclosing SEQ ID NO: 54 of the patent, and the production of the peptide recombinantly). In particular, the reference teaches that the peptides

may be produced by expression of expression vectors comprising nucleotide sequences encoding the peptides. Column 11, lines 42-55. In view of these teachings, it would have been obvious to those of ordinary skill in the art to make polynucleotides encoding SEQ ID NO: 1 for the recombinant production of the peptide.

12. Claims 23, 27, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabezon et al. (WO/97 04640), in view of Choo et al. (PNAS 88:2451-55), and Sarobe (supra). These claims read on compositions comprising full-length core proteins comprising the modified epitope of SEQ ID NO: 1, or on polynucleotides or vectors encoding the protein.

Cabezon teaches compositions for the induction of an immune response comprising recombinant HCV core protein. Claim 1, and page 2. While the reference does not teach the use of a core protein according to SEQ ID NO: 2, it does teach a core protein sequence comprising the CTL epitope modified in the Sarobe reference. SEQ ID NO: 3 of the reference. Thus, it would have been obvious to those in the art to use a core protein comprising the modified epitope as disclosed in Sarobe. Additionally, as Choo discloses an alternative HCV core protein sequence, and as the Cabezon reference indicates that any HCV core protein may be used, it would similarly have been obvious to those in the art to use a core protein comprising the sequence disclosed in the Choo reference but modified according to the teachings of Sarobe. Thus, motivation for these modifications are that Choo discloses a functional equivalent of the core protein disclosed in Cabezon, and that Sarobe discloses a means for improving the anti-HCV activity of compositions comprising these core proteins.

Those in the art would have had a reasonable expectation of success based on the teachings of Sarobe, the indication on page 5 of Cabezon the disclosed compositions would be useful for the induction of a CTL response, and on teachings in the art indicating that the core protein is able to induce CTL responses. See e.g., Ferrari et al., Hepatology 19: 286-95 (teaching that T-cells from patients infected with HCV were reactive with the core protein- and thus that this protein is able to induce such responses). The combined teachings of Cabezon, Choo, and Sarobe therefore render the claimed invention obvious.

***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 21-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 9-11, and 13-15 of U.S. Patent No. 6,685,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent would anticipate the present claims if applied as prior art, and because the present claims provide no non-obvious limitations over the claims of the prior patent.

***Conclusion***

15. No claims are allowed.

16. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Neville et al., J Clin Microbiol, 35: 3062-70. This reference teaches the core protein sequences of several isolates of HCV. However, none of these proteins comprises the sequence of SEQ ID NO: 1.
>
> Wentworth et al., Internat Immunol 8: 651-59. This reference teaches an HCV T-cell epitope comprising the sequence of SEQ ID NO: 1, except that the peptide comprises a Lysine at position 8 rather than an Alanine.
>
> Parker et al., J Immunol 149: 3580-87; and Maillere et al., Molec Immunol 32: 1073-80. These two references show that similar substitutions in different T-cell epitopes result in different (unpredictable) effects. For example, each of these references teaches a substitution of the native residue in position 8 of disclosed T-cell epitopes, but in each reference, different effects were seen in the different epitopes from those found in the epitope of present application.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 9/6/05

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600